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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,649	03/05/2002	Harold T. Hammel	Hammel -001	6107
38288	7590	05/04/2004	EXAMINER	
ROBERT J. YARBROUGH, ATTORNEY AT LAW 201 NORTH JACKSON STREET MEDIA, PA 19063			MCINTOSH III, TRAVISS C	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/090,649

Applicant(s)

HAMMEL, HAROLD T.

Examiner

Traviss C McIntosh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 10 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/14/03
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

The Amendment filed December 19, 2003 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 1-9 have been amended.

Claims 10-12 have been added.

Remarks drawn to rejections of Office Action mailed June 30, 2003 include:

112 1st paragraph rejection: which has been overcome by applicant's arguments and has been withdrawn.

112 2nd paragraph rejections: which have been overcome in part by applicant's amendments and arguments and have been withdrawn in part.

An action on the merits of claims 1-12 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

Response to Amendment

Newly submitted claims 10-11 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 10-11 require determining the caloric content of foodstuffs, which was not a requirement in the methods as previously claimed.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 10-11 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5 are drawn to methods of treating High Altitude Pulmonary Edema (hereinafter HAPE) comprising administering various foods which are defined by their function (i.e., foods selected so as to promote a change in bicarbonate concentration in a pulmonary arterial blood plasma from an arterial end to a venous end of a pulmonary capillary), which is seen to be missing a critical element. The claims fail to particularly point out the identity of the active agent (compound) to be used in the method instantly claimed. The current claim language is drawn to a method which is not described structurally or nomenclatorially; but rather by the active agent's mode of action, function or effect requisite to an activity produced by the method. The claim is missing the critical element, which is the particular or distinct identity of the active agent to be used in the method. Defining the agents structurally or nomenclatorially would be a more preferable way to define the subject matter instead of the current functional description.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 8-9, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Butler et al. (US Patent 6,511,964).

Claim 1 is drawn to a method of treating HAPE comprising the steps of ingesting a food which is defined by it's function (promotes a change in bicarbonate concentration), and refraining from eating other foods which are defined by their function (inhibits a change in bicarbonate concentration). Claims 2-5 provide that the foods ingested comprise a digestible carbohydrate (which is further defined by function). Claim 6 provides the ingested carbohydrate is glucose. Claim 8 provides that the foods which should not be eaten are foods which contain nitrogen, and claim 9 provides that the foods which should not be eaten are meat and legumes. Claim 12 is drawn to a method which comprises ingesting glucose or sucrose and refraining from ingesting carbohydrates other than glucose or sucrose and refraining from ingesting fats, meats, or legumes.

Butler et al. disclose a method of treating acute mountain sickness by administering ribose. It is noted, that the same population (persons at high altitude) is treated with the same active agent (carbohydrates – ribose) in the same concentrations (see abstract, for example), and therefor the method of Butler et al. inherently discloses the methods as claimed in the instant

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application. See *Ex parte Novitski*, (BdPatApp&Int) 26 USPQ2d 1389. Moreover, Butler et al. disclose a method wherein 3 subjects ingest glucose at 12,000' (see, column 8, lines 36-39). The method of administering only glucose to subject at 12,000' inherently anticipates the claims of the instant application. The same population is administered the same compound in the same concentration, thus, any disorder treated must be inherent in the method as taught by Butler et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Butler et al. (US Patent 6,511,964).

Claims 1-6, 8-9, and 12 are set forth supra. Claim 7 provides that the carbohydrate ingested is sucrose.

Butler et al. disclose a method of treating acute mountain sickness by administering ribose and/or glucose. It is noted, that the same population (persons at high altitude) is treated with the same active agent (carbohydrates – ribose) in the same concentrations, and therefor the method of Butler et al. inherently discloses the methods as claimed in the instant application. What is not specifically taught is the administration of sucrose.

It would have been obvious to one of ordinary skill in the art at the time of the invention to administer sucrose to alleviate the symptoms of hypoxia, as Butler et al. disclose a method of administering glucose at altitudes of 12,000'. Sucrose is known to be a disaccharide comprising glucose and fructose (a pentose like ribose). Obviousness based on similarity of structure and function entails motivation to make claimed compound in the expectation that compounds similar in structure will have similar properties. Where the prior art compounds essentially bracket the claimed compounds and are known to be effective as well known pesticides, for example, one of ordinary skill in the art would be motivated to make the claimed compounds in searching for new pesticides. See *In re Payne*, 606 F.2d 303, 203 USPQ 245, 254-55 (CCPA 1979).

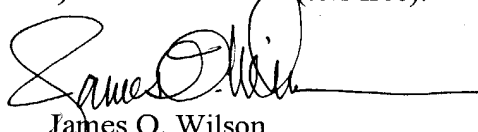
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Traviss C. McIntosh III
April 27, 2004



James O. Wilson
Supervisory Patent Examiner
Art Unit 1623